#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
TITBALL ET AL.	)	
Serial No. <b>10/070,882</b>	)	Art Unit: 1645
Filed: March 11, 2002	)	Examiner: S. J. N. Devi
For: RECOMBINANT MICROORGANISMS	)	

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### APPLICATION FOR PATENT TERM ADJUSTMENT

Sir:

In accordance with 37 C.F.R § 1.705(b), by submission of this Application for Patent Term Adjustment ("Application"), applicants request reconsideration of the Patent Term Adjustment (PTA) of 78 days indicated in the Notice of Allowance mailed September 4, 2008, in U.S. Patent Application Serial No. 10/070,882 ("present application"). According to applicants' determination, discussed in detail below, the correct PTA is 757 days. Applicant respectfully requests that the patent term adjustment indicated in the Notice of Allowance mailed August 21, 2008 be reconsidered in view of the statements below and in view of the holding in Wyeth et al. v. Dudas, 88 U.S.P.Q.2d 1538 (D.D.C. 2008).

Based on the holding in *Wyeth*, the term of the patent to issue in the present application is entitled to a total period of adjustment due to the U.S. Patent and Trademark Office (PTO) delay ("PTO delay") that includes <u>both</u> a period of delay due to pendency of the present application over three years, provided in 35 U.S.C. §154(b)(1)(B), and the delays provided in

I hereby certify that this correspondence is being electronically filed with the United States Patent & Trademark Office through its EFS-Web electronic filing system on December 4, 2008.

/christy k. flagler/

35 U.S.C. §154(b)(1)(A) that accrued during the first three years of pendency of the present application. The total period of adjustment due to the PTO delay ("total PTO delay") should then be reduced by a period of time during which the applicants failed to engage in reasonable efforts to conclude processing or examination of the application as specified in 35 U.S.C. §154(b)(2)(C) ("applicants delay"). Thus, the resulting correct PTA is 757 days.

The total PTO delay in the enclosed PTA History obtained from the Patent Application Information Retrieval Electronic System (PAIR) (Exhibit A) is 557 days. As calculated in the PTA History, the 557-day total PTO delay accounts for the delay provided in 35 U.S.C. §154(b)(1)(A) but does not account for the delay provided in 35 U.S.C. §154(b)(1)(B), namely, for 699 days of delay that accrued starting on the day after the date that is three years after the date on which the present application was filed and not including the period beginning on the date on which applicants filed a Request for Continued Examination (RCE). See 37 C.F.R. §1.703(b).

As provided in 35 U.S.C. §154(b)(2), to the extent the periods of delay provided in §154(b)(1)(A) and (B) overlap, the period of adjustment should not exceed the actual number of days the issuance of the patent was delayed. The 699-day delay that corresponds to the delay provided in 35 U.S.C. §154(b)(1)(B) does not overlap with 517 days of delay corresponding to the delay provided in 35 U.S.C. §154(b)(1)(A), which accrued during the first three years of pendency of the present application. The 699 day delay overlaps with the 40 days of delay corresponding to the delay provided in 35 U.S.C. §154(b)(1)(A)). Therefore, the issuance of the patent was delayed due to the PTO by 517 days during the first three years of pendency and by 699 days after the first three years of pendency.

Thus, the period of adjustment due to the PTO delay is 1216 days, not 557 days of the PTO delay shown in the PTA History. This 1216-day PTO delay should then be reduced by the number of days attributable to the applicants' delay. As detailed below in statement of the facts involved, applicants' delay is 459 days, not 479 days, as shown in the PTA History. After the reduction, applicants are entitled to 757 days of PTA, not 78 days shown in the PTA History and in the Notice of Allowance.

This Application is filed no later than the payment of the Issue Fee but after the mailing of a Notice of Allowance. As required in 37 C.F.R § 1.705(b), applicants submit the following:

- (1) The fee set forth in 37 C.F.R. §1.18(e); and
- (2) A statement of the facts involved.

STATEMENT OF THE FACTS INVOLVED

In support of this request and pursuant to 37 C.F.R. § 1.705(b), applicants provide the following statements:

## I. Statements under 37 C.F.R. §1.705(b)(2)(i)

The correct PTA credit due to PTO delay is 1216 days.

- (1) A credit of 507 days is due under §1.702(a)(1) and is due to the PTO's failure to mail a notification under 35 USC §132 or a notice of allowance within 14 months of the application's filing date;
- (2) A credit of 10 days is due under §1.702(a)(2) and is due to the PTO's failure respond to a reply under 35 U.S.C. §132 not later than four months after the date on which the reply was filed; and
- (3) A credit of 699 days is due under §1.702(b) and is due to the PTO's failure to issue a patent within three years of the filing date, not including any time consumed by continued examination of the application under 35 U.S.C. §132(b).

## II. Statements under 37 C.F.R. §1.705(b)(2)(ii)

The following dates are relevant to the time periods noted in section I above:

- (1) The relevant dates as specified in §1.703(a)(1) for the first part of the PTA credit is the application's filing date, March 11, 2002, and the mailing date of a first Office Action, September 29, 2004;
- (2) The relevant dates as specified in §1.703(a)(2) for the second part of the PTA credit is November 1, 2004, the date the Response to September 29, 2004, Office Action was received at the PTO, and the mailing date of the next Office Action, March 23, 2005; and
- (3) The relevant dates as specified in §1.703(b) for the third part of the PTA credit is the application's filing date, March 11, 2002, and the RCE filing date, February 8, 2007.

### III. Statements under 37 C.F.R. §1.705(b)(2)(iii)

The patent to issue from the present application is not subject to a terminal disclaimer.

#### IV. Statements under 37 C.F.R. §1.705(b)(2)(iv)

The following statements are required by 37 CFR §1.705(b)(2)(iv)(A) and list the circumstances during the prosecution of this application constituting a failure to engage in reasonable efforts to conclude processing or examination of the above-identified patent application as set forth in §1.704:

- (1) Supplemental Response to Restriction Requirement was filed on January 24, 2005, 84 days after the Response to Restriction Requirement was received at the PTO on November 1, 2005.
- (2) Response to Office Action mailed March 23, 2005, was received at the PTO on June 24, 2005, 1 day beyond the three months allowed under 37 C.F.R. §1.704(b); and

- (3) Response to Notice of Non-Compliant Amendment was received at the PTO on September 26, 2005, 94 days after Response to Office Action mailed March 23, 2005, was received at the PTO on June 24, 2005.
- (4) Supplemental Response to Office Action mailed March 23, 2005, was received at the PTO on November 22, 2005, 57 days after Response to Notice of Non-Compliant Amendment was received at the PTO on September 26, 2005.
- (5) RCE was received at the PTO February 8, 2007, 72 days beyond the three months allowed under 37 C.F.R. §1.704(b) to respond to Final Office Action mailed August 7, 2006.
- (6) Response to Office Action mailed May 2, 2007, was received at the PTO on October 29, 2007, 88 days beyond the three months allowed under 37 C.F.R. § 1.704(b); and
- (7) RCE was received at the PTO on June 16, 2008, 63 days beyond the three months allowed under 37 C.F.R. §1.704(b) to respond to Final Office Action mailed January 14, 2008.

Based on the above relevant dates, the total applicants' delay is 459 days.

# V. Conclusion

Applicant respectfully requests the PTA determined by the U.S. Patent and Trademark Office be reconsidered in light of the foregoing. Based on the total PTA credit and applicants' delay set forth above, the correct PTA for the patent to issue on the present application is 757 days.

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Respectfully submitted,

/elena s. polovnikova/

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Attorney Docket No. 41577-270459 (P1246)

# Exhibit A

10/070,882 RECOMBINANT MICROORGANISMS 2008::15:45:20

# **Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/070,882				
Filing or 371(c) Date:	03-11-2002	USPTO Delay (PTO) Delay (days): 557		
Issue Date of Patent:	- Three Years: -			
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	479	
Post-Issue Petitions (days):	+0	Total PTA (days): 78		
USPTO Adjustment(days):	+0	Explanation Of Calculations		

# **Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
09-04-2008	Mail Notice of Allowance		
09-03-2008	Document Verification		
09-03-2008	Notice of Allowance Data Verification Completed		
09-02-2008	Examiner's Amendment Communication		
06-18-2008	Date Forwarded to Examiner		
06-18-2008	Date Forwarded to Examiner		
06-16-2008	Request for Continued Examination (RCE)		63
06-18-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		Ŷ
06-16-2008	Request for Extension of Time - Granted		*
06-16-2008	Workflow - Request for RCE - Begin		曾
05-16-2008	Mail Examiner Interview Summary (PTOL - 413)		眷
05-12-2008	Examiner Interview Summary Record (PTOL - 413)		音
04-23-2008	Mail Advisory Action (PTOL - 303)		會
04-23-2008	Advisory Action (PTOL-303)		Ŷ
04-21-2008	Date Forwarded to Examiner		會
04-14-2008	Amendment after Final Rejection		會
02-13-2008	Miscellaneous Incoming Letter		*
01-14-2008	Mail Examiner Interview Summary (PTOL - 413)		Ŷ
01-14-2008	Mail Final Rejection (PTOL - 326)		4
01-07-2008	Final Rejection		
03-08-2007	Examiner Interview Summary Record (PTOL - 413)		
11-01-2007	Date Forwarded to Examiner		
10-29-2007	Response after Non-Final Action		88

10-29-2007	Request for Extension of Time - Granted	含
05-02-2007	Mail Examiner Interview Summary (PTOL - 413)	4
05-02-2007	Mail Non-Final Rejection	Ŷ
04-30-2007	Non-Final Rejection	
03-08-2007	Examiner Interview Summary Record (PTOL - 413)	
02-20-2007	Date Forwarded to Examiner	
02-08-2007	Request for Continued Examination (RCE)	92
02-20-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)	會
02-08-2007	Request for Extension of Time - Granted	會
02-08-2007	Workflow - Request for RCE - Begin	令
08-08-2006	Mail Final Rejection (PTOL - 326)	ł
08-07-2006	Final Rejection	
05-25-2006	Date Forwarded to Examiner	
05-23-2006	Response after Non-Final Action	
02-23-2006	Mail Non-Final Rejection 28	
02-21-2006	Non-Final Rejection	
12-06-2005	Date Forwarded to Examiner	
11-22-2005	Supplemental Response	57
09-30-2005	Date Forwarded to Examiner	會
09-26-2005	Response after Non-Final Action	94
09-15-2005	Mail Notice of Informal or Non-Responsive Amendment	會
07-05-2005	Date Forwarded to Examiner	會
06-24-2005	Informal or Non-Responsive Amendment after Examiner Action	Ŷ
06-24-2005	Response after Non-Final Action	1
03-23-2005	Mail Non-Final Rejection 22	
03-21-2005	Non-Final Rejection	
02-02-2005	Date Forwarded to Examiner	
01-24-2005	Supplemental Response	84
11-17-2004	Date Forwarded to Examiner	Ŷ
11-01-2004	Response to Election / Restriction Filed	*
06-11-2002	Information Disclosure Statement (IDS) Filed	
06-11-2002	Information Disclosure Statement (IDS) Filed	

03-11-2002	Request for Foreign Priority (Priority Papers May Be Included)	
03-11-2002	Request for Foreign Priority (Priority Papers May Be Included)	
11-01-2004	Workflow incoming amendment IFW	
09-29-2004	Mail Restriction Requirement	507
09-28-2004	Requirement for Restriction / Election	**
01-29-2004	IFW TSS Processing by Tech Center Complete	*
01-29-2004	Claims PTO	**
03-11-2002	Preliminary Amendment	Ť
11-12-2003	Date Forwarded to Examiner	4
10-14-2003	Response to a Letter to Comply with the Sequence Rules	
10-21-2003	CRF Is Good Technically / Entered into Database	Ť
09-10-2003	Mail Letter Requiring CRF (Unreadable, Non- Compliant, Not Submitted)	*
09-10-2003	CRF Diskette Unreadable / Did Not Comply / Required but Not Submitted	4
04-03-2003	Case Docketed to Examiner in GAU	*
06-25-2002	Application Dispatched from OIPE	8
06-20-2002	IFW Scan & PACR Auto Security Review	*
06-06-2002	Notice of DO/EO Acceptance Mailed	**
03-11-2002	CRF Disk Has Been Received by Preexam / Group / PCT	4
03-27-2002	CRF Is Good Technically / Entered into Database	Ŷ
03-11-2002	Initial Exam Team nn	\$

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